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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,008

02/01/2005

Fumitaka Goto

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4635

22852 7590 05/03/2007
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

05/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/523,008

Applicant(s)

GOTO ET AL.

Examiner

Laura L. Stockton, Ph.D.

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1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 2-11 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-16 is/are allowed.
- 6) ☒ Claim(s) 1 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/1/2005</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-16 are pending in the application.

Election/Restrictions

Applicant's election of Group I (Claims 1 and 12-16 - drawn to products) in the reply filed on April 5, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Claims 2-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no

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allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 5, 2007.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The Examiner has considered the Information Disclosure Statement filed on February 1, 2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrase "by the general formula (1)" should be changed to "by formula (1)" since "general" implies compounds not embraced by formula (1).

In claim 1, under the definition of variables R and R^1 , "in the phenyl ring" should be changed to "on the phenyl ring".

In claim 12, the phrase "by the general formula (41)" should be changed to "by formula (41)" since "general" implies compounds not embraced by formula (41).

In claim 12, under the definition of variables R^1 , R^K and R^L , "in the phenyl ring" should be changed to "on the phenyl ring".

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Nagarajan et al. (CA 101:211044, 1984).

Nagarajan et al. disclose the compound of CA Registry No. 92918-17-7, which is embraced by the instant claimed invention. Therefore, Nagarajan et al. anticipate the instant claimed invention.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffer {U.S. Pat. 3,493,582}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicant claims 4-nitro-imidazole compounds. Hoffer teaches, and claims, antitrichomonal 4-nitro-imidazole compounds that are structurally similar to the instant claimed compounds. See in Hoffer, for example, the compounds of formula (1) wherein R₂ is halogen, A is nitro (see formula (VI) in column 2), B is hydrogen, and R₁ is 2,3-epoxypropyl (column 1 and column 3; and especially Example 11 in columns 5-6).

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Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

The difference between the compounds of the prior art and the compounds instantly claimed resides in that the prior art is silent as to the stereochemistry of the 2,3-epoxypropyl group.

Finding of prima facie obviousness--rational and motivation (MPEP

§2142-2413)

A stereoisomer is not patentable over its known racemic mixture unless it possesses unexpected properties not possessed by the racemic mixture. *In re Anthony*, 162 USPQ 594, 596 (1969) and *In re Adamson*, 125 USPQ 233, 234 (1960).

One skilled in the art would thus be motivated to prepare stereoisomers of the compounds taught by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful as chemotherapeutic agents. The instant claimed invention would have been

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suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Allowable Subject Matter

Claims 13-16 are allowed.

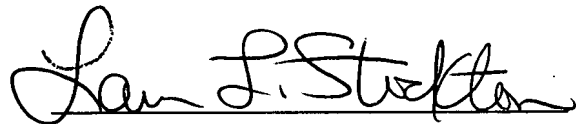
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

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Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, reading "Laura L. Stockton". The signature is fluid and cursive, with the first name "Laura" and last name "Stockton" clearly distinguishable.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

April 30, 2007